Lv

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,763	10/02/2003	Evgenia Mandrusov	50623.341	1625

7590 10/17/2007

Paul J. Meyer, Jr.
Squire, Sanders & Dempsey L.L.P.
Suite300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
CAMERON, ERMA C	

ART UNIT	PAPER NUMBER
1792	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,763	MANDRUSOV ET AL.	
	Examiner	Art Unit	
	/Erma Cameron/	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 07 August 2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-77 is/are pending in the application.

4a) Of the above claim(s) 24-29,33-44,46-55,61-63 and 67-77 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23, 30-32, 45, 56-60, 64-66 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Election/Restrictions

1. Applicant's election without traverse of A) the angiogenic substance of claim 45, B) iii and C) vi in the reply filed on 8/7/2007 is acknowledged.

Claims 24-29, 33-44, 46-55 and 61-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 67-77 were previously withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of Claims 32, 59 and 60 under 35 U.S.C. 112, second paragraph, is withdrawn because of the amendment filed 8/7/2007.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 64 had originally claimed "covering the inner surface", and was amended 8/7/2007 to read "temporarily placing a cover on the inner surface", which implies a "touching" relationship between the cover and the inner surface. This is new matter that is not supported by the specification as originally filed.

The applicant is requested to cancel new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

> subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 23, 32, 56 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Ragheb et al. (US 6,299,604).

Ragheb et al. ('604) teach a method of manufacturing a drug-eluting coating for a stent (col.6, line 65), the stent including a lumen (col. 7, line 1-2), i.e. tubular body having an outer surface and an inner surface (col.8, line 1-5). Ragheb et al. ('604) disclose that at least one bioactive material, i.e. the first coating, is posited (col. 7, line 65-67) on one surface of the structure and other surface will contain different bioactive materials, i.e. second coating. In this manner (col. 8, line 1-5) one or more bioactive materials or drugs may be delivered with a vascular stent to the blood stream from the lumen surface, i.e. inner surface of the stent, and a different treatment may be delivered on the vessel surface, i.e. outer surface of the stent. Ragheb et al. ('604) further teach (col. 4, line 61-64) the same bioactive material will generally not be posited on the different surfaces of the stent. In the other words, each surface of the stent structure will carry a different bioactive material.

Additionally, Ragheb et al. ('604) teach a range of drugs, medicaments and materials may be employed as the coating materials (col. 8, line 7-8), such as (col. 9, line 34-36) angioenine, i.e. an angiogenic substance and (col. 14, line 47-48), antiproliferative agent such as pacitaxel, which is capable of inhibiting smooth muscle cells proliferation or migration.

Response to Arguments

The applicant has argued that Ragheb et al. do not disclose an angiogenic substance on the inner surface and an antiproliferative on the outer surface.

The examiner's position is that one of skill in the art would know to place the angiogenic substance on the inner surface (where the blood is) and the antiproliferative on the outer surface (where the blood vessel cells are).

8. Claims 23, 45, 56, 58, 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber (US 6,517,888).

Weber ('888) teaches a method of manufacturing a drug-eluting coating for a stent (col. 5, line 21), the stent including a cylindrical body, i.e. a tubular body having an outer surface and an inner surface (col.2, line 1-2). The inner and outer surface of the stent can be coated with different materials (col. 2, line 37-38). The method comprises: forming a first coating on the inner surface of the stent (col.2, line2-3), the first composition including a first therapeutic substance capable of angiogenesis (col. 7, line 17); and applying a second composition to the outer surface of the stent, the second therapeutic substance capable of inhibiting migration or proliferation of smooth muscle cells (col.6, line 41).

As for claim 45, Weber ('888) teaches the angiogenic substance can be a hepatocyte growth factor (col. 6, line 17),

As for claim 58, Weber ('888) teaches the first and second coating materials may include a polymer (col. 5, line 35-36).

Response to Arguments

The applicant has argued that each class of agents can be placed on the outer surface or inner surface.

The examiner's position is that one of skill in the art would know to place the angiogenic substance on the inner surface (where the blood is) and the antiproliferative on the outer surface (where the blood vessel cells are).

9. Claims 23, 30-31, 64-66 are rejected under 35 U.S.C. 102(b) as anticipated by Loeffler (US 5,897,911).

Loeffler ('911) teaches a method of manufacturing a coating for a stent (col.1, line 50), the stent including a tubular body having an outer surface and an inner surface (see fig. 3) the method comprising: using a mandrel and/or mold, i.e. removable sheath to apply coating materials to the selected surfaces of the stent (col. 1, line 52-62). Loeffler ('911) teaches the coating materials including polymers (col. 2, line 54) and various therapeutic agents, antithrombins (col.3, line 6) and angiogenic substance such as fibroblast growth factor (col.3, line 21).

As for claims 64-66:

In one embodiment, Loeffler ('911) teaches the stent is first mounted about a core pin and pin cap (col.4, line 23-24, see fig. 2), after which the entire assembly is fitted inside an external mold. The coating material is subsequently injected (col.4, line 29-31) through the core pin or through the external mold to coat the inner or outer surface of the stent. Additionally, Leoffler ('911) teaches (col. 2. line 1-3) different coating materials, i.e. different therapeutic agents and different polymers, can be applied to selected surfaces of the stent..

Response to Arguments

The applicant has argued that each class of agents can be placed on the outer surface or inner surface.

The examiner's position is that one of skill in the art would know to place the angiogenic substance on the inner surface (where the blood is) and the antiproliferative on the outer surface (where the blood vessel cells are).

The applicant has additionally argued that the core pin is spaced apart from, not on, the interior surface of the stent. The examiner disagrees. Figure 3 shows a tapered mandrel 26 that fits snugly inside the stent 12.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 57 is rejected under 35 U.S.C. 103(a) as being anticipated by Ragheb et al. ('604) in view of Harish et al. (US 6,506,437).

Ragheb et al. ('604) teach that which is disclosed in the above. Ragheb et al. teach coating a drug-eluting stent by applying angiogenic substance on the inner surface of the stent and an antiproliferative agent on the outer surface of the stent. Ragheb et al. ('604) are silent concerning the stent having cavities in the inner and outer surfaces.

Harish et al. (‘437) teach a method of coating implantable stent (col. 2, line 54), the stent including a tubular body having an outer surface and an inner surface (see fig.2). Additionally, the stent has a plurality of cavities formed in virtually any preselected location of the stent surface (col. 4, line 47-51), i.e. the stent has cavities in the inner and outer surfaces. Harish et al. (‘437) teach applying a first coating to the outer surface of the stent (col. 2, line 23-26), wherein the coating compositions are applied to at least partially fill the cavities (col. 8, line 60-63). Harish et al. (‘437) teach the coating compositions include polymers (col. 5, line 10) and therapeutic substances such as angiogenic substances, anticoagulant and antiproliferative agents (col. 6, line 60-62).

Together, Ragheb et al. (‘604) teach the inner surface of the implant stent is coated with angiogenic substance that can be released to the blood stream and stimulate angiogenesis and the outer surface of the stent is coated with antiproliferative agents that are capable of exerting the therapeutic substance to the blood vessel wall to prevent the thrombosis of the artery, and Harish et al. (‘437) also teach a drug-eluting implant stent that is capable of local delivery of antiproliferative agents to the blood vessel and additionally, releasing the designed therapeutic substance in the manner of controlled rate by filling drug substance in the cavities and cover with topcoat polymeric coating. Given these teaching, Harish et al. (‘437) would have reasonably suggested coating the implant stent and cavities in inner and outer surfaces with the coating method of Ragheb et al. (‘604).

It would have been obvious to one of ordinary skill in the art to use the stent of Harish et al. (‘437) in the coating method of Ragheb et al. (‘604) with the expectation of successful results because Harish et al. (‘437) teach a method of delivering angiogenic and antiproliferative substance not only on the lesion site but also exerting therapeutic substances in an extended period of time.

Response to Arguments

The applicant has not presented specific arguments on this rejection.

12. The rejection of Claim 39 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Slaikeu et al. (US 6,663,607) is withdrawn because this claim has been withdrawn from consideration.

13. The rejection of Claims 42 and 52 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Bowlin et al. (US 2002/0,081,732) is withdrawn because these claims have been withdrawn from consideration.

14. The rejection of Claims 51 and 53 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Pierce et al. (US 2001/0,044,413) is withdrawn because these claims have been withdrawn from consideration.

15. The rejection of Claim 38 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Lane et al. (US 4,990,333) is withdrawn because this claim has been withdrawn from consideration.

16. The rejection of Claim 40 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Li et al. ("A peptide regulator of angiogenesis" Nat Med. 6(1), 6(3), page 49-55 (Jan and March 2000)) is withdrawn because this claim has been withdrawn from consideration.

17. The rejection of Claim 41 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Penta et al. ("Del 1 induces integrin signaling and angiogenesis by ligation of alphaVbeta3," J. Biol Chem, 16; 274 (April 1999)) is withdrawn because this claim has been withdrawn from consideration.

18. The rejection of Claims 44, 47,48 under 35 U.S.C. 103(a) as being unpatentable by Weber ('888) in view of Kovesdi et al. (US 2003/0,027,751) is withdrawn because these claims have been withdrawn from consideration.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erma Cameron/
Primary Examiner
Art Unit 1792

October 15, 2007